

USSN 09/618,129
Amendment and Response

REMARKS

Applicants have reviewed the Office Action mailed on November 16, 2004, and provide the following amendments and response. A petition for a three month extension of time is enclosed with this response; however, in the event a petition is required, this paper is to be considered such a petition. The Commissioner is authorized to charge any requisite fees to deposit account number 13-2725.

Claims 2, 3, 8, 9, 11-36, 42 and 43 are pending. Claims 11, 23-25, and 42 are amended. Claim 43 is added. No new matter is introduced.

Amendments to the Claims

Claims 11 and 23-25 are amended to clarify the claims and to correct for matters of form.

Claim 42 is amended to clarify that a primer extension product does not form when X and Y are the same nucleotide. No new matter is introduced.

Claim 43 is newly added. Basis for claim 43 is found in the specification as originally filed and in the claims. Applicant submits that no new matter is introduced.

Objections to the Specification

The Examiner objected to the specification because of a typographical error on page 13. Applicants have amended the specification to correct the typographical error; therefore, the objection is overcome.

Rejections Under 35 U.S.C § 102(b)

Claims 2, 3, 8, 9, 11-15, 17, 23-36 and 42 are rejected as allegedly anticipated by Fahy et al. (WO 96/30545). Applicants respectfully traverse this rejection.

Claim 42 is independent and claims 2, 3, 8, 9, 11-15, 17 and 23-36 ultimately depend from claim 42. Claim 42 is amended in pertinent part to recite that a labeled primer extension product results when Y and X are different nucleotides and wherein a primer extension product does not form when Y and X are the same nucleotide.

USSN 09/618,129
Amendment and Response

Applicants submit that Fahy et al. fails to disclose at least this element of the claims, and therefore, Fahy et al. cannot anticipate the claims.

Claim 42 is generally directed to a method of detecting variations of a nucleotide at a defined site of a nucleic acid. The claimed method uses primer extension reactions to produce a labeled primer when X and Y are not the same nucleotide. Importantly, the claimed method does not produce a primer extension product when X and Y are the same nucleotide.

Fahy et al. discloses a method for detecting nucleic acid variations using primer extension reactions to produce extension products of different sizes for nucleic acids having different sequences or mutations. See for example page 16 which provides in pertinent part:

"...the specific mixture [of nucleotides] is designed based on knowledge of the deviations between the related polynucleotides to ensure that each related polynucleotide produces an extension product that differs in length from the extension products of the other related polynucleotides and from the primer ..." (p. 16, l. 29-34).

Indeed, Fahy et al. discloses that the variations are detected by separating the extension products from another based on the relative size of each (e.g., on the basis of molecular weight). On page 7, lines 34-37, Fahy et al. discloses that "an extension product of unique length is formed for each of the related polynucleotide sequences" and "separating the primer and the extension products based on their respective lengths." Fahy et al. fails to disclose a method by which a labeled primer extension product forms when X and Y are different nucleotides and wherein a primer extension product does not form X and Y are the same nucleotide.

Applicants point out that although Fahy et al. discloses that their nucleotide mixture can contain two or three dNTP's and no chain terminating, base pairing entities, Fahy et al. does not disclose, teach, or suggest a method by which a labeled primer extension product forms when X and Y are different nucleotides and wherein a primer extension product does not form X and Y are the same nucleotide. Fahy et al repeatedly discloses that a primer extension product is produced in each reaction whether the nucleic acid sample contains wild-type or mutant sequences.

USSN 09/618,129
Amendment and Response

The Office Action emphasizes that Fahy et al. discloses "synthesis of the extension products is accomplished by polymerase extension of the primers until a template nucleotide is read or omitted which terminates synthesis." In response, Applicants point out that Fahy et al. discloses that a primer extension product is made in each reaction irrespective of whether a wild-type or mutant nucleotide is present in the sample. The claimed method differs from the method of Fahy et al. for at least the reason that the claimed methods produce a labeled primer extension product only when X and Y are not the same nucleotide and does not produce a primer extension reaction product when X and Y are the same nucleotide. Applicants respectfully submit that Fahy et al. fails to disclose at least this element of the claimed methods.

Because Fahy et al. fails to disclose each element of claim 42, Fahy et al. cannot anticipate claim 42 and the rejection is overcome. The remaining pending claims ultimately depend from claim 42 and therefore incorporate all of the elements of claim 42. Thus, claims 2, 3, 8, 9, 11-36 are not anticipated by Fahy et al. for at least the reasons that Fahy et al. fails to anticipate claim 42.

Rejections Under 35 U.S.C § 103

Claims 16 and 18-22 are rejected as allegedly obvious over Fahy et al. and further in view of Soderlund (U.S. 6,013,431). Applicants respectfully traverse the rejection.

Claims 16 and 18-22 ultimately depend from claim 42 and incorporate the limitations of amended claim 42. As noted above, Fahy et al. fails to disclose, teach or suggest all of the elements of amended claim 42. Soderlund fails to cure these deficiencies. To render a claim obvious, the combination of references must teach or suggest each element of claims. Because the combination of references does not teach or suggest all of the elements of the claims, claims 16 and 18-22 are not obvious. Applicants respectfully submit that the rejection is overcome.

New Claim 43

Although new claim 43 has not been rejected over the cited references, the cited references are discussed in so far as they may apply to claim 43.

USSN 09/618,129
Amendment and Response

New claim 43 includes a termination reaction in which an unlabeled terminator nucleotide and a primer extension reaction are performed in a single reaction vessel using a single type of primer so that a multi-labeled primer extension product only forms when the target nucleic acid has a variation of the target nucleotide. Applicant respectfully submits that the cited references fail to disclose or suggest claim 43 for the reasons provided below.

Fahy et al. discloses a method in which a primer extension reaction product is always produced and then determining whether a variation occurs in the target nucleotide by comparing the length of the primer reaction products produced. Soderland discloses a method in which multiple reaction vessels using at least two primers are used to determine the presence of a variation. Neither reference discloses or teaches a method using a single type of primer in a termination reaction and a primer extension reaction in a single vessel that produces a primer extension product incorporating a plurality of labeled products when the target nucleic acid comprises a variation. Thus, Applicant respectfully submits that new claim 43 is free of the art of record.

USSN 09/618,129
Amendment and Response

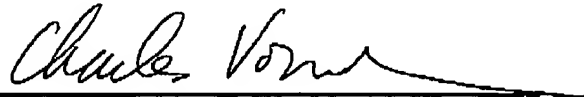
Conclusion

Applicants submit that the pending claims are in condition for allowance. Reconsideration and a Notice of Allowance are respectfully requested. In the event the Examiner believes a telephone call would expedite prosecution, the Examiner is invited to call the undersigned at 404-954-5061.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(404) 954-5100

Date: 5/16/05



Charles Vorndran
Reg. No. 45,315
CV:kaw